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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/869,813 | 01/03/2002 | Lawrence M. Boyd | MSD1-303/PC379.04 | 1340 |
| 52196 | 7590 | 10/09/2007 | | |
| KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709 | | | EXAMINER COMSTOCK, DAVID C | |
| | | | ART UNIT 3733 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/869,813

Applicant(s)

BOYD ET AL.

Examiner

David Comstock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,17,18,20,35-37,52,54,56 and 59-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15,17,18,20,35-37,52,54,56 and 59-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 July 2007 has been entered.

Allowable Subject Matter

The indicated conditional allowability of objected claims 12, 60, 65, 70 and 71 is withdrawn upon further consideration of the references to Brosnahan, III (5,645,598), Zdeblick et al. (5,669,909) and Michelson (5,593,409).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-15, 17, 18, 20, 35-37, 52, 54, 56 and 59-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (5,669,909; previously cited) in view of Michelson (5,593,409; cited by applicant).

Zdeblick et al. disclose a pair of interbody fusion devices 10 comprising an elongated generally cylindrical body having end walls 12 and 17, a side wall 16, and a hollow interior chamber 15 between the two ends (Fig. 2). One end 12 has flat discontinuities corresponding to discontinuities 22 in the side wall. The discontinuities allow the device to be nested against another device in a single disc space (see Fig. 6 and col. 7, lines 50-58). The side wall discontinuity extends along a length of the body aligned with the end wall discontinuity. The side wall discontinuity defines a plurality of side wall openings 24,25 to the interior chamber 15. The interbody fusion device 10 is formed of metal (see col. 5, lines 42-47). The outer surface defines threaded bone-engaging portions 18. The device includes a tool-engaging end 13 defining a tool engaging hole, e.g. a hex recess (see col. 7, lines 6-10). An osteogenic material is disposed within the chamber (see col. 5, lines 55-59 and col. 7, lines 50-58). Each side wall discontinuity appears to extend over approximately 25% of the circumference of the body (see Attachment A, corresponding to Fig. 4). The side wall discontinuity appears to extend over at least 50% of the length of the body (see Fig. 2). Osteogenic material could be introduced through the openings 24,25. Zdeblick also discloses preparing adjacent vertebrae and placing the devices in the intervertebral space to nest against each other (see col. 7, lines 50-58 and col. 10, line 48 - col. 11, line 51 and Fig. 6). It is also disclosed to pack osteogenic material prior to or after implanting the devices, i.e.

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"additional bone graft material" where "additional" implies some was added before implantation while the "additional" amount was added "in situ" (see col. 5, lines 55-59 and col. 7, lines 50-58). Zdeblick discloses the claimed invention except for the concave side wall and end wall discontinuities. Michelson discloses that flat side walls and concave side walls are functionally equivalent means of allowing two implants to fit within a single disc space (see Figs. 25 and 43, col. 12, line 59 - col. 13, line 3; and col. 15, lines 19-38). It would have been obvious to substitute concave side wall discontinuities for flat side wall discontinuities, in view of Michelson, as this would involve nothing more than the substitution of functionally equivalent means of accommodating two implants in a single disc space, known in the art at the time of the invention. It also would have been obvious to form the osteogenic material of demineralized bone, a calcium phosphate, bioceramic, bioglass, an osteoinductive factor, or other known materials or mixtures thereof, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 1, 2, 5-15, 17, 18, 20, 35-37, 52, 54, 56 and 59-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brosnahan, III (5,645,598; cited by applicant).

Brosnahan, III discloses a fusion spacer 10 comprising a generally cylindrical elongate body defining a side wall opening into an interior cavity 40. The first and second ends have a concave discontinuity 48,50. The side wall includes threads. The end walls are integrally fixed to the side wall. The spacer includes a tool-engaging end

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having a tool-engaging hole 32. The cavity is filled with an osteogenic material 42 (see col. 5, lines 31-45). The device includes the concave discontinuities to allow it to be closely nested with another implant (see col. 5, lines 46-62). The end walls have a profile defining a discontinuous arc 44,46 extending around at least 180 degrees of the circle and comprise the two concave surfaces 48,50 (see Fig. 14). The only difference between the device of Brosnahan, III and the claimed invention resides in the location of the opening or through slot with respect to the concavity. However, given that both of the principle features were known in the prior art, within a single reference no less, it is predictable that a person of ordinary skill in the art (that need not be Brosnahan, III) would rearrange their location, since it has been held that mere relocation of parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. It also would have been obvious to form the osteogenic material of demineralized bone, a calcium phosphate, bioceramic, bioglass, an osteoinductive factor, or other known materials or mixtures thereof, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

In response to Applicant's prior remarks regarding the applied references, the following is now noted.

Upon further consideration, Applicant's arguments against the applied references are not persuasive. The references disclose all the features of the claimed invention.

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The only differences amount to size and obvious modifications such as the location of known features and whether the device is separable or unitary. For example, making the end walls unitary would be obvious as it has been held that forming in one piece an article which has formerly been formed from multiple pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893). That the end wall is an opening through which osteogenic material is placed, does not change the teaching of obviousness. It is noted that the implant could be filled, then the end wall could be non-removably attached to the device. Regarding the strength of the implant given the size of the opening, it is noted that other materials or thicker walls could be used to make the implant stronger, despite the length of the opening. Making such modifications as changing the thickness of the walls or forming the implant from another stronger metal or alloy, again, is an established matter of obvious design choice for a person of ordinary skill in the art. It has been held that discovering the optimum or workable ranges, e.g., of wall thickness, involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Likewise, selecting a suitable material, e.g. a stronger metal or alloy, has been held to be within the general skill of a worker in the art and a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-

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4710. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



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